IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---|---|---|---|
| Applicant: | KNUDSON ET AL. | Examiner: | S. GILBERT |
| Serial No.: | 10/825,029 | Group Art Unit: | 3736 |
| Filed: | APRIL 14, 2004 | Docket No.: | 13033.4USC4 |
| Title: | METHOD AND APPARATUS TO TREAT CONDITIONS OF THE NASO-PHARYNGEAL AREA | | |

CERTIFICATE UNDER 37 CFR 1.8:
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on December 22 2005.

By: Kristine A. Wacek
Name: Kristine A. Wacek

**DECLARATION OF PAUL J. BUSCEMI, PH.D.**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

23552
PATENT TRADEMARK OFFICE

Dear Sir:

Paul J. Buscemi declares as follows:

1. In 2005, I became Vice President, Research & Development of Restore Medical, Inc., assignee of the above-referenced patent application ("Patent Application").
2. I submit this declaration in response to a July 1, 2005 Patent Office action in the Patent Application. I have reviewed the following in advance of this Declaration:
    a. The Patent Application
    b. The July 1, 2005 Patent Office action in the Patent Application
    c. U.S. Pat. No. 5,979,456 ("Magovern")
3. My relevant education is as follows:
    a. I received a B.S. degree in Physics from the University of Florida – Gainesville in 1968.
    b. Following a period of military service, I received a Ph.D. from the University of Florida – Gainesville in 1978. The Ph.D. is in biomaterials. My education and doctorate research was heavily focused on implant materials and tissue response

(including fibrotic response) on a wide variety of materials including polymers (including polyester, polytetrafluoroethylene (PTFE) and expanded polytetrafluoroethylene (ePTFE)), metals (including shape memory metals such as nitinol) and ceramics.

c. Following my Ph.D., I did post-doctorate work at the University of Florida – Gainesville until 1980.

4. My relevant work experience is as follows:
   a. From 1980 to 1983, I did surface chemistry work at Ashland Chemical, Ohio (this work did not include evaluating tissue response to implants).
   b. From 1983 to 1988, I worked for British Oxygen Corp. (BOG), New Jersey developing and evaluating polymer surface coatings and interactions with blood as part of developing bio-compatible coatings for catheters.
   c. From 1988 to 1985, I worked for SciMed (a division of Boston Scientific), Maple Grove, Minnesota developing and evaluating cardiovascular stents. This work included evaluating tissue response of stent materials including nitinol.
   d. From 1995 to 2005, I worked for Advanced Biosurface, Minnetonka, Minnesota. This work included evaluating tissue response to orthopedic implants.
5. Based on my review of the documents described in paragraph 2, above, my education and experience, I make the following observations and conclusions regarding U.S. Pat. No. 5,979,456 ("Magovern"):
   a. Magovern describes various concepts for treating obstructive sleep apnea. My remarks will focus on the concepts disclosed with reference to Figures 8-10 of Magovern. The implants of Magovern are described as one or more suture-like threads of shape-memory material inserted into the musculature as described in Magovern on column 7, lines 25-59. Various shape-memory materials are described in column 5, lines 48-56 and include nitinol (nickel titanium alloy), CuZnAl and CuAlNi alloys.
   b. The implants of Magovern are selected to have no impact on the pharyngeal wall or other anatomical structures except when activated by application of energy from a source. The application of energy can be heating (e.g., by electrical current) or cooling.

c. The material of Magovern would not have a significant fibrotic response when implanted in the musculature of the pharyngeal wall. The description of a "suture-like thread" would lead one of ordinary skill in art to recognize Magovern is using extremely thin shape-memory metal threads of about 0.5 millimeters in diameter. Such metals are well known as having a low fibrotic response. That is one of the reasons such shape-memory metals like nitinol are used in cardiovascular stents where fibrosis is an event to be avoided. Any fibrosis that might result from Magovern would be extremely miniscule. For example, for a 0.5 millimeter diameter suture-like thread of nitinol or the other shape-memory metals described in Magovern, the thickness of a surrounding fibrosis layer might be in the order of 20 to 50 microns which is equivalent to a thickness of a few layers of cells of the tissue.

d. The miniscule fibrotic response, if any, of the material of Magovern would not alter the dynamic response of the tissue to air flow. One of ordinary skill in the art reading the Patent Application would recognize that the Patent Application is describing, in certain embodiments, implant of materials that are selected to induce fibrosis in a material amount with material meaning imparting to the tissue a resistance to deformation.. Magovern and the other cited references do not show or suggest such materials.

6. I make this statement based upon my own information and knowledge and the facts recited in this Declaration are true and correct to the best of my knowledge. The foregoing statements are made of my own knowledge and are true. I hereby acknowledge I am warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.

22 Dec 05
Date

Paul J. Buscemi, Ph.D.